

June 30, 2004

U.S. Department of Health and Human Services
Agency for Healthcare Research and Quality

RE: Docket ID 2004S-0170, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggest Priority Topics for Research

Dear Sir/Madam:

Pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), we are pleased to submit for your consideration a number of recommendations for cost-effective research projects to be conducted within the Medicare End Stage Renal Disease patient population. These suggestions are presented on behalf of the Chief Medical Officers of the four largest dialysis service public companies (DaVita, Fresenius Medical Care, Gambro, and Renal Care Group), which serve more than 120,000 Medicare beneficiaries with End Stage Renal Disease ("ESRD").

As you know, the cost of care for these ESRD patients exceeds \$17 billion dollars annually. We strongly believe that timely interventions in the dialysis unit where these patients are seen 3 times a week can significantly reduce the overall cost of care, and particularly the cost of hospitalizations by reducing the average length of stay (currently more than 14 days per year per beneficiary). Given the rising costs associated with providing appropriate care to the Medicare ESRD patient population, we believe these proposed projects should be a priority for the agency under MMA Section 1013.

Below we present our recommendations, including a brief description of the proposed research project. We would be pleased to present a more detailed and annotated description of these projects if the agency is interested in exploring them in more detail. We appreciate your consideration of these recommendations, which we believe will assist the agency in improving the quality, effectiveness, and efficiency of the Medicare program for current and future ESRD patients.

Recommendations

1. Hypothesis: Access blood flow monitoring will reduce graft thrombosis and lead to reductions of catheter utilization and an increase in native fistulae rate.

Access thrombosis is often a “catastrophic” event for ESRD patients, and often precipitates admission to the hospital and insertion of temporary blood access in the form of catheters. The use of these catheters is associated with increased incidence of infections, sepsis, antibiotic use, and hospitalizations.

Use of a simple blood flow measurement during dialysis can predict with a high degree of accuracy the probability of thrombosis. With use of this technique, accesses that are likely to thrombose can be treated prophylactically and reduce or avoid the cost of initial as well as subsequent hospitalizations for catheter placement, infections, etc.

This technique of blood flow monitoring requires the use of available equipment and 30 minutes of a technician’s time, and can be done once every three months per patient. However, under complex CMS rules, this technique is not reimbursed if performed in the dialysis unit; instead, a more complex and expensive procedure requiring outpatient hospital services are paid for.

Proposal: We propose a study where the cost of access related admissions for patients in facilities using this technique (currently without reimbursement) is compared to access related hospitalizations for patients in facilities that do not use this technique prospectively.

2. Hypothesis: A study of the relevance of “Clinical Performance Measures” (CPM) in determining dialysis patients’ outcomes.

For the past several years, CMS, through its “ESRD Networks”, has collected data on the dose of dialysis, anemia management (hemoglobin) and nutritional status (serum albumin level), as well as the types of dialysis accesses (fistulas, catheters, grafts).

The relationship between the dose of dialysis, hemoglobin, serum albumin, and mortality is an exponential relationship with a steep increase in mortality below a minimum level of dose of dialysis and hemoglobin. However, above a certain value, the relationship is “flat”, with no further reduction in mortality.

In 2003, collected measures of dialysis dose and hemoglobin are in the “flat” region of the curve and patients do not seem to benefit from a further increase in those values. Nevertheless, CMS continues to maintain an emphasis on further improvements in these areas. However, one area that has been neglected is the nutritional status of ESRD patients. Sequential yearly follow-ups have shown no improvement in the nutritional status of patients as assessed by serum albumin. This is predominately due to the enormous regulatory burden imposed by CMS for provision of adequate oral or intravenous nutrition for ESRD patients.

We propose a study of nutritional supplements during dialysis (oral and when indicated intradialytic) to see if such interventions can reduce the severity and extent of hospitalizations, which are severely and adversely impacted by malnutrition in these ESRD patients.